

3 a sample collection device comprising a relatively rigid strip [forming a handle member]
4 having a handle end and a collection end, said collection end having attached thereon a collection
5 pad for collecting and drying the sample containing the analyte, [said collection pad capable of
6 having at least a portion thereof removed from] wherein the device includes a means for
7 facilitating removal of at least a portion of the collection pad from the relatively rigid strip to
8 recover the analyte for detection or measurement by laboratory analysis; and
9 an information card for providing information about the patient.

Add new claim 21 as follows:--

1 21. The kit of claim 19 wherein the means for removing at least a portion of the
2 collection pad comprises an aperture formed through the collection end of the strip.--

REMARKS

Applicant has developed a device for collecting and drying a liquid biological sample at a first location, and then mailing the dried sample to a clinical laboratory remotely located from the first location for analysis. A preferred version of Applicant's device includes a relatively rigid strip having a handle end and a collection end. The handle end of the strip can be used for manipulating the device during the sample collection step (e.g., manually placing the device into a urine stream). Attached to the collection end of the strip is a collection pad for collecting a liquid sample. The collection pad is made of a material that can (a) absorb the liquid sample and (b) allow the sample to dry in a relatively short period. The device also includes a means for facilitating removal at least a portion of the collection pad from the strip. This means can be,

e.g., a hole punched through the collection end of the strip so that a standard hole puncher can be used to remove a portion of the collection pad from the device for analysis. Among other things, the device is advantageous in that it prevents accidental leakage of a liquid sample during transport (a dried sample being less like to leak than a liquid sample), and allows rapid removal of the sample from the device to facilitate analysis at the clinical laboratory.

Claims 1-20 were pending in the subject application. By this Amendment, claims 1, 5, 6, 7, 12, and 19 have been revised; claims 13-18 have been canceled; and new claim 21 has been added. Therefore, claims 1-12 and 19-21 are now pending in this application. Consideration of these claims is respectfully requested.

Election/Restriction

Claims 13-18 were withdrawn from further consideration in this case as being drawn to a non-elected invention. Applicants now affirm the April 6, 2000 telephonic election, and, in order to expedite prosecution of this case, have canceled claims 13-18 without prejudice.

Objections

In response to the objection of the drawings as being informal, Applicants will file formal drawings upon allowance of the claims.

Rejection Under 35 U.S.C. § 102(b)

In the Office Action, claims 1-7, and 10-12 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lee (U.S. 4,260,392). Lee is directed to a device for obtaining a precise

aliquot of a sample by diffusing the sample into a gel mass for a controlled period of time. (Col. 3, lines 50-53). Lee's device includes a gel for quantitatively absorbing a liquid sample contained within a well formed in a support. In the examples provided (Examples I-III), analysis proceeds within 3-10 minutes after exposure of the gel to the liquid sample is stopped. Analysis is apparently performed without removing the gel from the support. See, e.g., col. 6, lines 5-7 "[t]he well is generally centered on the support 11 at a location wherein the gel will intersect the light beam of a suitable photometer or spectrophotometer," and Examples I-III. Lee does not teach drying a liquid sample on the gel; nor does it teach removal of the gel from the support for analysis.

Applicants submit that amended independent claim 1 is not anticipated by Lee because Lee does not disclose various elements included in claim 1. See, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). In particular, the device of amended claim 1 includes "a collection pad (for collecting and drying the sample). .," and "a means for facilitating removal at least a portion of the collection pad from the relatively rigid strip." In contrast, Lee's device does not include a means for facilitating removal of all or part of its gel portion to recover an analyte for laboratory analysis to recover the analyte for detection or measurement by laboratory analysis. Rather, Lee apparently teaches analyzing a sample absorbed into the gel while the gel is still on the device by, e.g., spectrophotometry. In addition, while Lee's gel may be useful for absorbing a sample, no indication is made that it is adapted for drying a liquid

intended use
apertures?

With regard to claim 7, the Office Action indicated that Lee's device includes an aperture. Applicants respectfully disagree with this assertion, and point out that a common dictionary definition of "aperture" is an opening. In contrast to the aperture of Applicants' device, Lee's apparatus has a well (i.e., well 12) or "at least some sort of depression" (Col. 6, lines 58-59) that can be filled with a gel, not an aperture. To clarify the difference between Lee's well and Applicants' aperture, claim 7 has been amended to recite an aperture formed "through" (not "in") the relatively rigid strip.

For the foregoing reasons Applicants submit that amended independent claim 1, and therefore claims 2-7 and 10-12 which depend from claim 1 are not anticipated by the Lee reference. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 USC § 102(e)

In the Office Action, claim 19 was rejected under 35 U.S.C. § 102(e) as being anticipated by Ray et al. (U.S. 6,036,659; hereinafter, the "'659 patent'"). The '659 patent relates to a device for collection and separation of a biological sample such as blood. The device includes a separation member for separating cellular material from acellular fluid (e.g., serum), so that the acellular fluid can be collected in a collection member for later analysis.

With due respect, Applicant believes the Office Action misconstrues the device shown in FIG. 1 of the '659 patent by indicating that it includes "a relatively rigid strip 13 forming a handle member having a handle end 11 and a collection end 14 and a collection pad 12 (FIG. 1), and wherein the strip has an aperture formed at the collection end which exposes a portion of the collection pad. . . ." Referring to column 7, lines 36-52 of the '659 patent, the device of FIG. 1 is

described as including a "collection member 11," not a "handle end 11;" a "separation member 12," not a "collection pad 12;" a "first free end 13" of collection member 11, not a "relatively rigid strip 13;" and a "second free end 14" of collection member 11, not a "a collection end 14 of a relatively rigid strip." Additionally, the device of FIG. 1 does not feature a relatively rigid strip. Moreover, Applicants do not understand what portion of the device shown in FIG. 1 of the '659 patent corresponds to the "aperture" described in the present application. Accordingly, Applicants request clarification or withdrawal of this rejection.

Rejection Under 35 U.S.C. § 103 (a) In View of Lee (U.S. 4,260,392)

In the Office Action, claims 1, 8, and 9 were rejected under 35 U.S.C. § 103 as being unpatentable over Lee (U.S. 4,260,392). More specifically, the Office Action combined the teaching of Lee (see above) with a statement that:

It is well-known in the art to immobilize BSA in the matrix of a collection pad. It would have been obvious to one of ordinary skill in the art to do so because it is also well known that BSA is very useful in preserving dried blood or urine samples.

In view of the above argument that Lee does not anticipate amended independent claim 1, Applicants submit that a rejection under 35 U.S.C. § 103 is not proper because even if one were to combine Lee with Examiner's statement regarding BSA, one would still be missing at least two aspects of the device of amended claim 1, namely "a collection pad for collecting and drying the sample . . .," and "a means for facilitating removal at least a portion of the collection pad from the relatively rigid strip." And as claims 8 and 9 depend from claim 1, Applicants submit that they too are patentably unobvious of the combination of Lee and Examiner's statement. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103 (a) Over Ray et al. (U.S. 6,036,659) In View Of Brown Jr. (U.S. 5,921,396)

Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray et al., 6,036,659 (the '659 patent), in view of Brown Jr. (U.S. 5,921,396). More specifically, the Office Action arrived at the rejection by combining the teaching of the '659 patent with Brown, Jr., which the Office action asserts "teaches a combination urine collection kit and shipping means, wherein the kit comprises sample collection tubes (12, 14) and a urine collection cup 40 (abstract; FIGS. 1-22)."

In view of the above argument that the '659 patent does not anticipate amended independent claim 19, Applicants submit that a rejection under 35 U.S.C. § 103 is not proper because even if one were to combine the elements of the device shown in FIG.1 of the '659 Patent with the urine cup disclosed in the Brown, Jr. reference, one would still be missing several aspects of the kit of claim 20. For example, in contrast to the Office Action's assertion, for the reasons provided above relating to the 35 U.S.C. § 102(e) rejection of claim 19, the device within the kit of claim 20 does not include a "handle end 11," a "collection pad 12," "relatively rigid strip 13," or "a collection end 14 of a relatively rigid strip." Additionally, the device shown in FIG. 1 of the '659 patent does not feature a relatively rigid strip or an aperture. Therefore, withdrawal of this rejection is requested.

Patentability of New Claims

New claim 21 depends from amended claim 19, and is therefore believed to be patentable.

Conclusion

Claims 1-12 and 19-21, as amended, are now pending in the application; claims 13-18 having been canceled and new claim 21 having been added by this Amendment. Claims 1, 5, 6, 7, 12, and 19 have hereby been amended in an effort to clarify the claimed invention. Applicant submits that currently pending claims are supported throughout the specification and are patentable over the prior art. No new matter has been added.

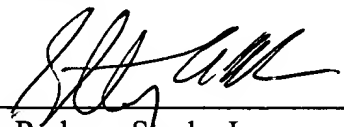
Applicants submit that this application is now in full condition for allowance, which action is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 17-0055.

Applicants invite the Examiner to call the undersigned if clarification is needed on any matter within this Amendment, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Date: 7/11/00

Respectfully submitted,



J. Rodman Steele, Jr.
Registration No. 25,931
Stanley A. Kim, Ph.D., Esq.
Registration No. 42,730
QUARLES & BRADY LLP
222 Lakeview Avenue, Suite 400
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000